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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/856,044

08/03/2001

Plamen A. Demirev

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05/10/2005

EXAMINER

LIN, JERRY

MILLEN, WHITE, ZELANO & BRANIGAN, P.C.

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ARLINGTON, VA 22201

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 05/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/856,044

**Applicant(s)**

DEMIREV ET AL.

**Examiner**

Jerry Lin

**Art Unit**

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 2-5, 7-13, 15 and 16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-5, 7-13, 15, and 16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

Applicants' arguments, filed February 3, 2005, have been fully considered and they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied.

#### ***Status of the Claims***

Claims 1, 6, and 14 are cancelled.

Claims 2-5, 7-13, 15, and 16 are pending.

Claims 2-5, 7-13, 15 and 16 are rejected.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 2 recites the limitation "the sequence database" in line 1. This limitation does not appear previously in the instant claim or in the claim from which it depends. There is insufficient antecedent basis for this limitation in the claim.

Claim 3 recites the limitation "the sequence database" in line 1. This limitation does not appear previously in the instant claim or in the claim from which it depends. There is insufficient antecedent basis for this limitation in the claim.

Claim 4 recites the limitation "the mass spectrometry" in line 1. This limitation does not appear previously in the instant claim or in the claim from which it depends. There is insufficient antecedent basis for this limitation in the claim.

Claim 5 recites the limitation " the mass spectrometry" in line 1. This limitation does not appear previously in the instant claim or in the claim from which it depends. There is insufficient antecedent basis for this limitation in the claim.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claim 2, 4, 5, 7, 8, 11-13, 15, and 16 are rejected under 35 U.S.C. 102(a) as being anticipated by Yates III (Journal of Mass Spectrometry, January 1998).

Regarding claims 8, 12, 13, and 15, Yates III teaches a method for using sequence databases to identify amino acid sequence obtained by mass spectrometry wherein the database is searched for intact, undigested proteins (page 7, column 1, first full paragraph; page 7, column 2, last paragraph); a sample that comprises a plurality of proteins from one or more unknown microorganisms (page 13, column 2- page 14, column 2); a database where molecular weight is deduced from nucleotide or protein sequence information (page 7, column 2, last paragraph – page 8, column 1 and Figure 3).

Regarding claim 2, Yates teaches the database may be a protein sequence database (page 8, Figure 3).

Regarding claim 4 and 5, Yates teaches that data may be obtained by electrospray on a time of flight or a MALDI-TOF (page 5, column 1 and 2).

Regarding claim 7, Yates teaches performing mass spectral analysis on a sample comprising one or more microorganisms (page 13, column 2- page 14, column 2).

Regarding claim 11, Yates III teaches the method can comprise enzymatic digestion of a protein sample (page 7, column 2, first full paragraph).

Regarding claim 16, Yates teaches inputting molecular weights from a mass spectrum as in claim 16 (page 8, column 1 and Figure 3).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

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not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 3, 9, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yates III (Journal of Mass Spectrometry, January 1998) in view of Wang et al. (Rapid Communications in Mass Spectrometry).

Yates III is applied as above.

Yates III does not teach where the sequence database is a nucleotide sequence database or wherein the sample comprises at least two different species of microorganisms.

Regarding claim 3, Wang et al. teach that the mass spectral patterns should be used to identify and search for protein biomarkers via their observed masses, rather than relying on spectral pattern differences such as differences in spectral peak magnitudes, and that an integrated approach using these protein masses can involve a peptide database (the sequence database can be a protein sequence database) or relating the protein masses to gene sequences that code for their production (the sequence database is a nucleotide sequence database (see page 463, column 2; paragraph 4; and page 459, column 1 bridge paragraph)).

Regarding claim 9, Wang et al. teach that one goal is to be able to identify and differentiate between different species of bacteria cells present in 'real world samples'

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(the sample comprises at least two different species of microorganisms (page 456, column 1, paragraph 1).

It would have been obvious to one of ordinary skill in the art to combine the teaching of Yates III with the methods of Wang et al., since Yates III and Wang et al. both teach methods for identifying proteins in a sample by using mass spectrometry results to search peptide/protein databases. Furthermore, Wang et al. suggest a method that combines MALDI, electrospray ionization, enzyme chemistry, tandem MS and peptide database is being developed. Yates III discloses all of these methods in his review of mass spectrometry.

Claims 13 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yates III (Journal of Mass Spectrometry, January 1998) in view of Yates III et al. (US 5,538,897).

Yates III (Journal of Mass Spectrometry) is applied as above.

Yates III does not teach wherein the sequence database comprises NCBI, Swiss Prot, or EMBL database.

Yates III et al. (US 5,538,897) teaches the sequence database may be GenBank, Swiss-PROT, or EMBL database as in claim 10 (column 3, lines 53-67).

It would have been obvious for one of ordinary skill in the art to combine the above references to gain the benefit of having more databases to which to compare protein data. The same author discloses both references, and Yates III (Journal of

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Mass Spectrometry) reviews the method disclosed in Yates III et al. (US 5,538,897) on pages 9-12.

### ***Applicant's Response***

The applicant's response is now moot in light of the newly applied art in the instant office action. However, the Examiner would like to note that claim 13, as it is written, also encompasses determining molecular weight with peptides, not just intact undigested proteins. Claim 13 states that a database is searched for the molecular weight of whole proteins whose molecular weight was determined from a mass spectrum of a sample. There is no limitation, in the claims, on how the mass spectrum is to be performed. Furthermore, a search may be conducted for intact undigested proteins without using the intact undigested protein. For example, a marker may be used to search for a gene in a gene database. The actual entire gene sequence is not used, however the marker is sufficient to search for the gene. Similarly, a method a protein or protein fragment may be used to search for the molecular weight of intact proteins.

### ***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Lin whose telephone number is (571) 272-2561. The examiner can normally be reached on 6:30-3:00, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D. can be reached on (571) 272-0718. The fax phone



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number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JL

*Marianne P. Allen*

MARIANNE P. ALLEN  
PRIMARY EXAMINER

*5/8/05*

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